Translation

PCT/JP2003/010826

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference AO-F8PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2003/010826	International filing date (*day/month/year*) 27 August 2003 (27.08.2003)	Priority date (*day/month/year*)
International Patent Classification (IPC) or national classification and IPC A61L 27/40, 27/42, 27/44		
Applicant OGISO, Makoto		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 12 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25 March 2004 (25.03.2004)	02 December 2004 (02.12.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/010826

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ The international application as originally filed/furnished

☒ the description:

pages 1, 2, 6, 7, 12-14, 16-20, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* 3-5, 8-11, 15 received by this Authority on 26 August 2004 (26.08.2004)

☒ the claims:

pages 2-6, 9-16, 18, 19, 22-26, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* 1, 17 received by this Authority on 26 August 2004 (26.08.2004)

pages* _____ received by this Authority on _____

☒ the drawings:

pages 1/6-6/6, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☒ the claims, Nos. 7, 8, 20, 21

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP03/10826

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-6, 9-19, 22-26	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-6, 9-19, 22-26	NO
Industrial applicability (IA)	Claims	1-6, 9-19, 22-26	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 04-240454 A (Nippon Electric Glass Co., Ltd.) August 27, 1992
Document 2: EL DEEB, M. et al., Osteogenesis in composite grafts of allogenic demineralized bone powder and porous hydroxylapatite, JOURNAL OF ORAL AND MAXILLOFACIAL SURGERY, 1989, Vol. 47, No. 1, p. 50-6
Document 3: JP 03-191963 A (Mitsubishi Mining & Cement Co., Ltd.) August 21, 1991
Document 4: JP 2001-137328 A (OLYMPUS OPTICAL CO., LTD.) May 22, 2001
Document 5: WO 95/13102 A1 (IMPLANT INNOVATIONS, INC.) May 18, 1995
Document 6: JP 2003-517888 A (Henogen SA) June 3, 2003
Document 7: IGNJATOVIC, N. et al., A study of HAp/PLLA composite as a substitute for bone powder, using FT-IR spectroscopy, Biomaterials, 2001, Vol. 22, No. 6, p. 571-575

Document 1 cited in the international search report describes a porous implant material made of crystallized glass wherein the osteogenesis promoting material is either adhered to or impregnated in the crystallized glass porous body (claim 1), and it lists decalcified bone powder as the osteogenesis promoting material (Par. No. 0013; page 3, Examples).

Document 2 states that excellent osteogenesis is observed after transplantation of a complex of autologous decalcified bone powder and porous hydroxyapatite (see Abstract).

Document 3 describes a calcium phosphate bone prosthesis with micropores of 0.5 μm or less that is a porous body having a three-dimensional reticulate structure provided with communicating void channels (see claim 1).

Document 4 describes a bone prosthesis containing a bone inducing factor and porous β-tricalcium phosphate that has pores with diameters of 50-1,000 μm and pores with diameters of 5 μm (claim 4) or less.

Document 5 describes an implant that is surgically implantable in living bone, and it describes a method for modifying the surface thereof wherein grit is impacted with the surface of the implant to improve the bonding between the implant and the bone (see Claim 1; page 1, lines 8-11, etc.)

Document 6, which was cited in a written opinion dated September 21, 2004, describes the use of bone particles to induce bone formation (see claims 15 and 16, etc.), and it states that particles of unmodified bone are preferred as those bone particles (see claim 25, Par. No. 0013).

Document 7 describes a mixed implant of autologous bone powder and a complex of hydroxyapatite/poly-L-lactide (Abstract, etc.), and it states that the autologous bone powder can be obtained by pulverizing the bone of a mouse femoral region (see page 572, Materials and Methods).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box V:

oClaims 1, 5, 6, and 9-16

Documents 1-7 above do not describe the inventions of claims 1, 5, 6, and 9-16, and therefore these inventions are novel.

When the inventions of the above claims are compared with the inventions described in documents 1 and 2, whereas decalcified bone powder is used in the invention described in document 1, living bone powder is used in the inventions of the above claims, and they differ in that respect.

However, document 6 states that it is preferable to use unmodified bone powder to induce bone formation, and document 7 describes transplantation using bone powder that is actually obtained by pulverizing living bone.

It is demonstrated by these descriptions that bone material that has not been decalcified, i.e., bone material from living bone, can be used to induce bone formation, and in the induction of bone formation, bone material from living bone has an effect that is preferable to modified bone material.

Because decalcified bone powder is used to induce bone formation in documents 1 and 2 above, this examination finds that persons skilled in the art can easily focus on the common aspects of this problem, and use bone powder that is not decalcified, i.e., bone powder from living bone, in the inventions described in documents 1 and 2 in the same manner that the decalcified bone powder is used, or with the expectation of obtaining a superior effect in inducing bone formation.

Moreover, this examination finds that using powder obtained from living bone does not provide a particularly outstanding effect in comparison with the use of decalcified bone.

Furthermore, although document 2 does not describe impregnating fine bone powder in a porous structural body, document 1 describes a method whereby bone powder is dispersed in physiological saline and then the porous body is immersed in that physiological. Thus, this examination finds that persons skilled in the art can easily include bone powder in the porous structural body by adopting a method similar to that described in document 1.

Moreover, this examination finds that no particularly outstanding effect is provided thereby.

As a result, the inventions of claims 1, 5, 6, and 9-16 do not involve an inventive step with respect to documents 1, 2, 6, and 7.

However, in a written reply dated November 18, 2004, the applicant asserted that the present invention does involve an inventive step by pointing out that:
The porous structural body impregnated with bone in the present invention provides the effects of
(a) containing a fine bone powder that differs from that described in documents 6 and 7;
(b) displaying excellent bone regenerative capability; and
(c) requiring only a small amount of collected bone when autologous bone is used.

The above assertions of the applicant are considered below.

(Continued to next page)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box V:

With respect to (a), even though the particle size of the bone particles described in documents is larger, that does not change the fact that based on the descriptions in documents 6 and 7 bone material that is not decalcified, i.e., bone material from living bone can be used to induce bone formation and in the induction of bone formation, bone material from living bone has an effect that is preferable to modified bone material.

With respect to (b), in light of the explanation provided in the Description, this examination finds that using powder obtained from living bone does not provide a particularly outstanding effect in comparison with the use of decalcified bone.

With respect to (c), the scope of the claims in this application includes cases in which the bone powder that is used is not from autologous bone, but this examination does not find that this effect is particularly outstanding. Even if autologous bone were to be specified, in consideration of the fact that the matrix material is porous in the inventions described in documents 1 and 2, this examination finds that the amount of decalcified bone used would be just as small as in the inventions of this application, and if bone powder that is not decalcified, i.e., bone powder from living bone, is used in the inventions described in documents 1 and 2, it is a foreseeable effect from the descriptions in the cited documents that the amount of powder would be lessened.

As a result, the assertions of the applicant cannot be accepted.

oClaims 2 and 3

In the inventions of the above claims the pore size, etc., of the porous structural body is specified.

However, in the field of artificial bone, etc., it is common practice to use a porous material as an implant, and it is public knowledge that porous material with the kind of pore size specified in claims 2 and 3 of this application can be used as an implant (see documents 3 and 4).

Moreover, descriptions in documents 1, 2, 6, and 7 show that that bone-forming capability is enhanced by mixing bone powder into the implant, and especially the descriptions in documents 6 and 7 show that bone powder obtained by pulverizing living bone can be used. Therefore, this examination finds that persons skilled in the art can easily use a porous material containing bone powder obtained by pulverizing living bone in the inventions of documents 3 and 4 with the expectation of a similar effect.

Furthermore, this examination finds that the effect obtained thereby is not particularly outstanding.

As a result, the inventions of claims 2 and 3 do not involve an inventive step with respect to documents 1-4, 6 and 7 above.

oClaims 4, 17-19 and 22-26

As shown in document 5 above, the fact that bonding with the surrounding bone can be improved by roughening the surface of an implant is publicly known, and this examination finds that persons skilled in the art can easily roughen the surface in the inventions described in documents 1-4 with the expectation of a similar effect.

Furthermore, this examination finds that the effect obtained thereby is not particularly outstanding.

As a result, the inventions of claims 4, 17-19 and 22-26 do not involve an inventive step with respect to documents 1-7 above.